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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/380,826	11/22/99	CHAPPEL	R DAVIE79.001A

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EXAMINER

HINES, J
ART UNIT PAPER NUMBER

1645
DATE MAILED:

14.
03/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/380,826

Applicant(s)
Chappel et al.

Examiner
Ja-Na Hines

Group Art Unit
1645



☒ Responsive to communication(s) filed on Nov 22, 1999

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-126 is/are pending in the application

Of the above, claim(s) 21-74 and 76-123 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-20, 75, and 124-126 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-126 are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 14

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of the restriction in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the groups are related by a special technical feature. This is not found persuasive because the inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. Group I is drawn to an isolated bacterium which is different from any other methods because the bacterium of Group I requires none of the steps list in the method groups (Groups II, IV, V and VII). The bacterium of group I has a different structure, sequence or deposit number then the groups. No other group is drawn to a isolated bacterium,, therefore these products have different features.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

2 This application has been filed with drawings which are acceptable for examination purposes only. The drawings are objected to for the reasons set forth in the attached PTOL-948.

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Specification

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). However, the abstract from the international application will be used in the instant application.
4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.
5. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

6. Claim 12 is objected to because of the following informalities: The claim recites the "foetal". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2, 19 and 20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. In order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MEP. 2402-2411.05, Applicant may provide assurance of compliance showing that:

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and
- (e) the deposit will be replaced if it should ever become inviable.

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This requirement is necessary when a deposit is made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each member State.

8. Claims 1-20, 75 and 124-126 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites "a derivative bacterium thereof". The specification does not teach how to make derivative bacterium thereof. The term "derivative bacterium thereof" is vague and indefinite, and it is unclear what characteristics are needed to determine whether an unknown bacterium thereof could be considered a derivative bacteria. The specification neither discloses a definition for a derivative bacterium thereof, nor does it teach a requisite amount of retained qualities needed or characteristics necessary to determine derivative bacteria thereof. Therefore the claim is vague and indefinite.

9. Claim 2 is vague because of the recitation of the phrase "growth characteristics". It is unclear how to determine which growth characteristics need to be exhibited. It is unclear if only temperature and media reagents are the only characteristics required or if there are requisite time periods for specific levels of growth. Therefore, it is unclear which characteristics "growth characteristics" includes and does not include.

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10. Claims 3-10 are indefinite because it recites the phrase "capable of". The claim does not denote whether the bacterium will or will not performing the function suggested in each claim.

Suggested claim language for the bacterium is "a bacterium which infects/ grows/ produces/ induces."

11. Claim 11 recites "reduced farrowing". It is unclear how to define reduced. There is no requisite level of farrowing set forth, therefore it is unclear how to define "reduced". Neither the claims nor the specification teach how to define if farrowing is reduced. Therefore the claim is unclear.

12. Claim 13 has the same problem as claim 11, because it recites "increased weaning-to-mating".

13. Claim 16 has the same problem as claim 1, because it recites "derivatives thereof".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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14. Claims 1-2 and 15-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Perolat et al., (EMBL U60594). The entry in the EMBL database is described as a characterization and phylogenic analysis of *Leptospira fainei* species isolated from Australian pigs. The source of the organism is from the strain Hurstbridge, wherein the product is a 16S ribosomal RNA sequence. The sequence is 1481 base pairs long. Therefore this entry teaches an isolated pathogenic *Leptospira* bacterium as required by the claims.

15. Claims 1-2 and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Hookey (EMBL Z21634). The entry in the EMBL database is described as a phylogeny of *Leptospira* and related spirochetes. The source of the organism is from *Leptospira inadai* and the strain Lyme, wherein the product is a 16S ribosomal RNA sequence. This sequence is 1374 base pairs long.

Therefore this entry teaches an isolated pathogenic *Leptospira* bacterium as required by the claims.

16. Claims 1-6 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Perolat et al., (Abstracts). Perolat et al., teaches molecular and phenotypic characterization of Hurstbridge strains as a new genomic species of pathogenic *Leptospira*. Is it known that pathogenic *Leptospira* can cause reproductive problems in pigs. The scientist isolated a strain and recorded its phenotypic characteristics to include a growth range of 13°-30°C which is in between the pathogenic and saprophytic species and azaguanine test. The research found provides evidence

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that there is a new serovar designated Hurstbridge. Finally, the Hurstbridge strain is important because the seroepidemiological study give evidence of potential public health issues

Therefore Perolat et al., (Abstract) teaches the invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perolat et al., (EMBL U60594) or Hookey (EMBL Z21634) or Perolat et al., (Abstracts) in view of Chappel et al., (Manipulating Pig Production). Perolat et al., (EMBL U60594), Hookey (EMBL Z21634) and Perolat et al., (Abstracts) have been discussed above, however none teach that *Leptospira* can infect humans. Chappel et al., (Manipulating Pig Production) teaches that Leptospirosis is more than meets the eye. Pathogenic strains of *Leptospirosis* is known to affect pigs reproductive performances, while human leptospirosis of pig origin is an important zoonosis. Also their research showed evidence of a new previously unrecognized serovar of *Leptospira*.

Therefore, it would have been obvious at the time of applicant invention to have known information should human infection by *Leptospira* bacterium as taught by Chappel et al., (Manipulating Pig Production) and apply it to the known *Leptospira* bacteria as taught by Perolat et al., (EMBL U60594) or Hookey (EMBL Z21634) in view of Perolat et al., (Abstracts),

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because Chappel et al., (Manipulating Pig Production) teaches that human *Leptospira* infection is an important field of research.

18. Claims 8, 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perolat et al., (EMBL U60594) or Hookey (EMBL Z21634) or Perolat et al., (Abstracts) in view of Chappel et al., (Pig Research Report). Perolat et al., (EMBL U60594), Hookey (EMBL Z21634) and Perolat et al., (Abstracts) have been discussed above, however none teach the *Leptospira* effects on the reproduction system. Chappel et al., (Pig Research Report) teach that infection of *Leptospira* can cause infertility, abortions, still births and is associated with seasonal infertility (page 3). The serovars can also cause early embryonic loss, however vaccination against the *bratislava* serovar can improve the farrowing rate in herds (page 6). The isolates used in the study were grown at 13°C in the presence of 8-azaguanine (page 4). Also a partial sequence of the 16S ribosomal RNA gene was obtained and sequence homology was compared (page 4). See the table on page 4 which shows the sequence homology between the researched isolate and other species of *Leptospira*. Other research methods taught the detection of *Leptospira* from bovine urine (page 5). Their research points to a previously undiscovered leptospiral serovar which is a member of the pathogenic species *Leptospira inadai* and a serovar within the *L.inadai* (page 5). Table 2 discloses pigs from which tissues were cultured in an effort to isolate *Leptospira*, where several pigs had the Hurstbridge serovar isolated (page 13).

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Therefore, no more than routine skill would have been required to use known infection capabilities of *Leptospira* as taught by Chappel et al., (Pig Research Report) with the isolated *Leptospira* bacterium of Perolat et al., (EMBL U60594) or Hookey (EMBL Z21634) or Perolat et al., (Abstracts) because Chappel et al., (Pig Research Report) teaches that reproductive problems are well known to be associated with *Leptospira* infections in pigs and bovines.

19. Claims 5-8, 10, 12, and 124-126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perolat et al., (EMBL U60594) or Hookey (EMBL Z21634) or Perolat et al., (Abstracts) in view of Haake et al., (US Patent 6,643,754. Perolat et al., (EMBL U60594), Hookey (EMBL Z21634) and Perolat et al., (Abstracts) have been discussed above, however none teach that *Leptospira* with a pharmaceutically acceptable diluent. Haake et al., (US Patent 5,643,754) teaches that *Leptospira* is a widespread zoonotic disease caused by pathogenic strains of *Leptospira* which are capable of infecting most mammalian species (col. 1 lines 20-25). Infection in livestock causes loss due to abortion, stillbirth, infertility, decreased milk production and death (col. 1 lines 27-30). One embodiment teaches *Leptospira* proteins may be comprised in pharmaceutical compositions useful for inducing immune responses in animals (col. 7 lines 30-34). Preparations include sterile or aqueous or non-aqueous solutions, suspension, emulsions and other like examples (col. 7 lines 45-50).

Therefore, it would have been obvious at the time of applicants invention to combine *Leptospira* with a pharmaceutically acceptable diluent as taught by Haake et al., with the

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bacterium of Perolat et al., (EMBL U60594) or Hookey (EMBL Z21634) or Perolat et al., (Abstracts) because Haake et al., states that such compositions may induce an immune response in animals.

Prior Art

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chappel et al., (Abstracts) teaches growth characteristics of a new genospecies and serogroup Hurstbridge.

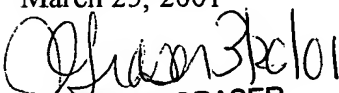
21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines

March 25, 2001


JENNIFER E. GRASER
PRIMARY EXAMINER